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OCT - 7 2002

Ms. Paula Turner
Label Specialist
Young Living Essential Oils
250 South Main Street
Payson, Utah 84651

Dear Ms. Turner:

This is in response to your letters of August 30, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Young Living Essential Oils is making the claim "May reduce the risk of heart disease" for its product **Super B**.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent a disease (i.e., heart disease). This claim does not meet the requirements of 21 U.S.C. 343(r)(6)¹. This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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The notification does not identify whether the claim for this product may be intended as a claim subject to 21 U.S.C. 343(r)(1)(B) rather than 21 U.S.C. 343(r)(6). Information on "health claims" may be found on FDA's internet web site at <http://www.cfsan.fda.gov/~dms/ds-labl.html>.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with the first name "John" and last name "Foret" clearly distinguishable.

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

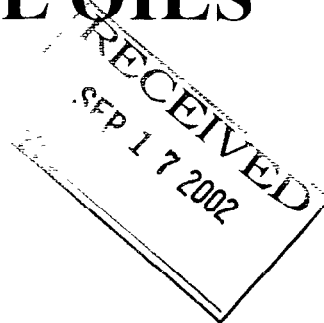
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

August 30, 2002

Office of Nutritional Products,
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. Street S.W.
Washington, D.C. 20204


Young Living
ESSENTIAL OILS™



Re: Notification for Statements on Dietary Supplement Labeling

Dear Sir/Madam:

This notification is being submitted on behalf of Young Living Essential Oils, Payson, Utah, a distributor of dietary supplement products (hereafter "Young Living").

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343 (r) (6), and in accordance with the authorized provisions of 21 CFR § 101.93 (a), your Agency is hereby notified that Young Living proposes to make and/or has made statements of "nutritional support", as described in 21 U.S.C. § 343 (r) (6) (A), for its dietary supplements as follows:

<u>Product Name</u>	<u>Statement(s)</u>
Super B	May reduce the risk of heart disease. Supports a positive outlook and healthy energy levels.
Stevia Extract	A dietary supplement that supports pancreas function. Helps maintain blood sugar levels that are already within the normal range.
Stevia Select	A dietary supplement that supports pancreas function. Helps maintain blood sugar levels that are already within the normal range. Supports healthy intestinal flora. Promotes calcium, potassium, and magnesium absorption.

The undersigned certifies on behalf of Young Living Essential Oils that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,


Paula Turner, Label Specialist

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